

Remarks

Claims 1-8 are pending in the subject application. By this Amendment, claims 1, 2, 3, and 6 have been amended. Support for these amendments can be found throughout the subject specification including, for example, at page 2, lines 5-9; page 3, lines 16-24 and lines 28-34; and Figures 2A-2C, 3B, 4A-4D, 5A-5D, and 6B. The undersigned avers that no new matter is introduced by this amendment. Accordingly, claims 1-8 are currently before the examiner.

The amendments to the claims have been done to lend greater clarity to the claimed subject matter and to expedite prosecution. The amendments to the claims should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Initially, the title of the subject application has been objected to. By this Amendment, the applicant has amended the title and, accordingly, respectfully requests reconsideration and withdrawal of the objection.

Claims 1-8 have been rejected under 35 U.S.C. §101 as non-statutory subject matter. By this Amendment, claims 1 and 2 have been amended, and the applicant believes that the cited claims are now directed to statutory subject matter. The applicant appreciates the Examiner's helpful suggestions. Accordingly, the applicant respectfully requests the reconsideration and withdrawal of this ground of rejection.

Claims 1-8 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection has been addressed by amendments to claims 1 and 6. Thus, the applicant avers that the claims as currently presented particularly point out and distinctly claim the subject matter of the applicant's invention. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim 1 has been rejected under 35 U.S.C. §102(b) as being anticipated by Nagamoto (JP 8-257046). The applicant respectfully traverses this rejection because the abstract and Figures of the Nagamoto patent fail to teach each and every element of the claimed invention. Specifically,

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Nagamoto is silent with respect to both the claimed invention's pointed annular rims and one or more compressible haptics.

In order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). The applicant submits that Nagamoto fails to disclose, at a minimum, at least two features of the claimed intraocular lens.

For instance, the claimed intraocular lenses provide one or more haptics that are compressible in the plane of each lens. Angled haptics, like those illustrated in the figures of the cited reference and in particular, figure 5, by definition do not compress in the plane of the lens. Moreover, angled haptics typically tilt under compression allowing the annular rim to become lifted, thereby allowing cells to migrate into the central optical zone.

Additionally, the lenses illustrated in Nagamoto's figures do not contain **pointed** annular rims. The purpose and constitution are silent with respect to any annular rims around the rim of Nagamoto's optic. Moreover, the only appendage to the optic, a projecting strip, is ring-shaped. Additionally, none of the figures disclose a pointed annular rim. The figures, particularly figures 5 and 6, do not illustrate a pointed rim around the optic. In fact, the area wherein the projecting strip and supports extend from the optic is rounded. Thus, neither the figures nor the brief description support a lens having a pointed annular rim. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 1, 2, 7 and 8 have been rejected under 35 U.S.C. §102(c) as being anticipated by Lai *et al.* (U.S. 2004/0002757). The applicant traverses this ground of rejection because Lai *et al.* fail to teach one or more haptics compressible in the planes of the lens and a pointed annular rim. Lai *et al.* disclose an intraocular lens having a flange radially positioned along the periphery of its optic and two haptics. The applicant respectfully points out that the Lai *et al.* flange exhibits an arcuate shape (*i.e.*, curved like a bow) where the anterior and posterior surfaces of the flange meet. (paragraph [0028], Figures 5 and 6). In contrast, the annular rim of the applicant's claimed invention forms a point.

Additionally, the cited reference teaches two angled haptics. The direction of biasing force in the cited references' haptics is in the direction of the posterior optic surface. In contrast, the one or more haptics of the claimed invention compress in a plane normal to the eye's optical surface. Accordingly, Lai *et al.* fail to teach both the pointed annular rims and the compressible haptics of the claimed invention, and the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(e).

Claims 1-3 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Grendahl (U.S. Patent No. 4,781,717). The applicant traverses this ground of rejection because Grendahl fails to suggest an intraocular lens having a pointed annular rim. In fact, Grendahl provides a lens having a rim with a **rounded** edge (column 1, lines 28-43; column 2, lines 1-5 and lines 58-61; claim 1).

Of course, a finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, the prior art is devoid of any teaching of the particular pointed annular rim now claimed by the applicant. It is only the applicant's disclosure that provides such a teaching, and it cannot be used to reconstruct the prior art for a rejection under 35 U.S.C. §103. This was specifically recognized by the C.C.P.A. in *In re Sponnoble*, 56 C.C.P.A. 823, 405 F.2d 578, 585, 160 U.S.P.Q. 237, 243 (1969):

The court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Srock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield the applicant's invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the Federal Circuit, to support a rejection under 35 U.S.C. §103, “[b]oth the suggestion and the expectation of success must be founded in the prior art . . .” *In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). The

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applicant respectfully submit that the prior art does not disclose or suggest the applicant's intraocular lens.

The purpose of the rounded rim edge of Grendahl's lens is to "prevent any cutting or wearing through the equator or other point of contact with of [sic] the capsular bag." (column 1, lines 33-35). Not only did it not suggest the particular annular rim edge of the applicant's invention, it failed to disclose any other shaped rim that could provide the requisite cutting or wearing protection. Consequently, the only suggestion for providing a lens with a pointed intraocular lens is supplied by the applicant's own invention.

Moreover, Grendahl fails to teach or suggest a particular intraocular lens that is useful for preventing epithelial cells from migrating across the posterior lens capsule. The applicant submits that the combination of both a pointed annular rim in conjunction with one or more compressible haptics inhibit posterior capsular opacification. However, the only rim edge shape suggested by Grendahl would promote this undesired migration because epithelial cell migration is blocked by sharp or square edges, not by round edges. Accordingly, the applicant respectfully requests reconsideration and withdrawal of this aspect of the rejection under 35 U.S.C. §103(a).

Claims 1 and 4-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Knolle (U.S. Patent No. 4,588,405), in view of Nagamoto (JP 8-257046). The applicant traverses this aspect of the rejection under 35 U.S.C. §103(a) and submits that the combination of references do not teach each and every element of the claimed lenses. For one, neither Knolle nor Nagamoto teach or suggest a pointed annular rim around the optic. As noted above, Nagamoto does not even disclose an annular rim, much less a pointed annular rim. Instead, it discloses several supporting pieces that extend from the optic and are ring-shaped.

Moreover, the applicants respectfully point out that the reduction in posterior capsular opacification associated with the lens of the claimed invention is surprising (*i.e.*, the reduction is not suggested by either of the cited references.) The applicant discovered that the combination of one or more haptics that compress in the plane of the lens and a pointed annular rim have a synergic effect on the reduction of posterior capsular opacification. This particular synergy is not suggested by

Knolle or Nagamoto. The applicant respectfully points out that the desirability of the claimed lens is evident from the example disclosed in the instant application.

The Federal Circuit has expressed the importance of secondary evidence, including unexpected results, in refuting obvious rejections.

[I]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of prior art was not. It is to be considered as part of all the evidence, not just when the decisionmaker remains in doubt after reviewing the art.

Stratosflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

The applicant respectfully points out that the instant application sets forth numerous data that illustrate the superior posterior capsular opacification (PCO) reduction associated with the claimed lenses. The example (pages 4-7) demonstrates a comparison between the claimed lenses (designated lens B) and lenses without the pointed annular rim (designated lens A). Briefly, the claimed lenses exhibited reduced intensity scores for both central and peripheral PCO, and in many instances, the claimed lenses produced scores of 0 grade. The instant application discusses the superior results of the claimed lenses below:

Table 1 summarises the results of the PCO scoring done from a posterior (Miyake-Apple) view. In Table 1, OD (*oculus dexter*) refers to the right eye, OS (*oculus sinister*) to the left. In each eye, central and peripheral PCO scores were lower for lens B, and higher for lens A. The average central PCO scores for lenses [A] and [B] were 0.90 and 0.39 respectively. The average peripheral scores for A and B were 1.85 and 0.83 respectively. This illustrates the desirability of a lens of the invention.

(page 6, lines 20-26).

A particularly desirable lens is a lens of claim 4. The haptics of such a lens are substantially resistant to tilting, thereby maintaining contact between the annular rim and the capsular sac. Also, the haptics of a lens of claim 4 resist contraction of the lens. When the capsule contracts, it contracts tightly over the annular rim, thereby creating an excellent seal.

In view of the superior results associated with the claimed invention and the failure of the references to suggest a pointed annular rim, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

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In view of the foregoing remarks, and the amendments to the claims, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16, 1.17, or 1.492 as required by this paper to Deposit Account No. 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

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